K093270

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

AUG 27 2009

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of WMT Composite DBM.

Submitted By:	Wright Medical Technology, Inc.
Date:	September 24, 2008
Contact Person:	Ryan M. Belaney Sr. Regulatory Affairs Specialist/Product Development Engineer (as of 2/10/09)
Proprietary Name:	WMT Composite DBM
Common Name:	Bone Void Filler
Classification Name and Reference:	21 CFR 888.3045 – Resorbable Calcium Salt Bone Void Filler Device – Class II
Device Product Code and Panel Code:	Orthopedic/87/MQV

DEVICE INFORMATION

A. INTENDED USE

WMT Composite DBM resultant paste is intended for use as a bone graft substitute to be injected or digitally packed into open bone voids/gaps that are not intrinsic to the stability of bony structure of the skeletal system (i.e., the extremities and pelvis) to cure in-situ. These open bone voids may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The paste provides a bone graft substitute that resorbs and is replaced with bone during the healing process.

The WMT Composite DBM paste cured in situ provides an open void/gap filler that can augment provisional hardware (e.g. K-Wires) to help support bone fragments during the surgical procedure. The cured paste acts only as a temporary support media and is not intended to provide structural support during the healing process.

The WMT Composite DBM Core Decompression Procedure Kit, consisting of a bone void filler and manual surgical instruments, is intended to be used during core decompression procedures. The bone void filler component resorbs and is replaced by bone during the healing process. The bone void filler included in the WMT Composite DBM Core Decompression Kit is not intended to be used as a load bearing device.

WMT Composite DBM is provided sterile for single use.

B. DEVICE DESCRIPTION

The design features of the WMT Composite DBM Kit are substantially equivalent to the design features of the predicate devices. A brief description of the WMT Composite DBM implant and a summary of additional performance/marketing claims are provided below.

IMPLANT DESCRIPTION

WMT Composite DBM consists of a calcium sulfate, calcium phosphate, and demineralized bone matrix bone void filler consisting of a powder component and an aqueous mixing solution. When the two components are mixed, according to directions, an injectable paste is formed which subsequently hardens via hydration reactions.

NON-CLINICAL PERFORMANCE/MARKETING CLAIMS

Accelerated healing compared to PRO-DENSE®:* At 6 weeks, the percentage of new bone formation within the WMT Composite DBM defects was approximately the same as for PRO-DENSE® treated defects although there was less residual material in the WMT Composite DBM defects at this time point compared to PRO-DENSE®. Compared to PRO-DENSE®, WMT Composite DBM showed accelerated and more complete healing as evidenced by new bone formation across the width of the defect.

Accelerated healing compared to autograft:* Compared to autograft and normal bone, WMT Composite DBM showed accelerated new bone formation at 13 and 26 weeks. This was evident by the slightly higher stiffness, the greater amount of newly formed bone, and statistically significantly greater compressive strength shown for WMT Composite DBM. By comparing the 26-week clinical and contact radiographs and gross cross-sectional images and histological images, there appeared to be little to no apparent differences between defects filled with either WMT Composite DBM or autograft. Comparison of percentage of new bone, compressive strength, and modulus of elasticity showed no statistically significant differences between the materials at 26 weeks.

Bone remodeling to normal bone at 13 weeks:* From 6 to 13 weeks, the amount of new bone formation in the WMT Composite DBM defects increased. At 13 weeks, the WMT Composite DBM material had substantially remodeled compared to the 6-week time point. From 13 to 26 weeks, the amount of new bone formation for WMT Composite DBM was sustained and the amount of residual material continued to decrease. Further, at every time point, a comparison of WMT Composite DBM to normal bone shows no significant differences for percentage new bone, compressive strength, and modulus of elasticity.

Following the same test design as the predicate, ALLOMATRIX®, the osteoinductive property of WMT Composite DBM was confirmed.

*All claims are based on a critically sized canine proximal humerus defect model. It is unknown how results from the canine model compare with clinical results in humans.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, type of interface, operating principles, shelf life, and design features of the WMT Composite DBM are substantially equivalent to the previously cleared predicates. Additionally, the safety and effectiveness of the WMT Composite DBM is adequately supported by the substantial equivalent information, materials data, and testing results provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

AUG 27 2009

Wright Medical Technology, Inc.
% Mr. Ryan Belaney
Sr. Regulatory Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

Re: K083270
Trade Name: WMT Composite DBM
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV, MBP
Dated: August 3, 2009
Received: August 11, 2009

Dear Mr. Belaney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K083270

Device Name: WMT Composite DBM

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WMT Composite DBM is provided sterile for single use only.

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K083270

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number _____

Prescription Use √ OR Over-The Counter Use ____
(Per21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)